

**MOUTH GUARD USE IN NCAA BASKETBALL
PART ONE: CURRENT MOUTH GUARD PRACTICES IN NCAA BASKETBALL
PROGRAMS; PART TWO: SUBJECTIVE ANALYSIS OF MOUTH GUARDS IN NCAA
BASKETBALL ATHLETES: A PILOT TRIAL; PART THREE: PUBLIC HEALTH
IMPLICATIONS OF NOT MANDATING MOUTH GUARD USE IN NCAA
BASKETBALL**

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A thesis submitted to the faculty of the University of North Carolina at Chapel Hill in partial fulfillment of the requirements for the degree of Master of Science in Endodontics, in the Department of Comprehensive Oral Health in the Adams School of Dentistry

Chapel Hill
2020

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ABSTRACT

James Edward Goglia: **MOUTH GUARD USE IN NCAA BASKETBALL
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(Under the Direction of Ibrahim Duqum)

Basketball is considered as a sport with a very high incidence of dental trauma relative to other sports. Studies have established that mouth guards (MGs) can reduce the incidence of dental trauma during basketball activities. However, the National Collegiate Athletic Association (NCAA) has not imposed a mandatory equipment rule for basketball athletes to wear MGs during gameplay. It is hypothesized that the disconnect between the evidence-based recommendations to wear MGs during basketball activities and the low levels of MG compliance is multifactorial. To investigate this hypothesis, a three-part NCAA-focused study was created. Part One is a nationwide survey of all NCAA basketball programs current MG practices. Part Two is composed of a prospective NCAA basketball athlete trial to acquire subjective data on various commercially available MGs. Part Three is a review of the public health implications for low levels of MG use in NCAA basketball athletes.

ACKNOWLEDGEMENTS

I wish to acknowledge the following people for their willingness to help me through this journey:

Ibrahim Duqum for your mentorship, passion, and expertise for sports dentistry

Peter Tawil for your continued guidance, “get it done” and tough love attitude, and friendship

Sigurður Saemundsson for your leadership with statistics and vision for the third manuscript

Dr. Monroe Elkin for providing the self-adapted mouth guards for the study

All of my co-residents: Dan Crossen, Lesleigh Payne, Krista Anderson-Strange, Nic Pettit, Elisa

Arnarsdottir, Michael Mittelsteadt, Chris Ammons, Ethan Hamer, Alabbas Hussein, My Trinh,

Fei Fei Huang, Iryna Hyrvenko Daline, and Zack Mohorn for your input and camaraderie

through it all

My amazing wife, Katelyn Goglia, for your love, support, and sacrifice to help me get to where I am today

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LIST OF ABBREVIATIONS

ADA	American Dental Association
AE	Athlete Exposure
AS	Athlete Seasons
Div. I	Division I
Div. II	Division II
Div. III	Division III
IASD	International Academy of Sports Dentistry
MG	Mouth guard
NBA	National Basketball Association
NCAA	National Collegiate Athletic Association
NFSH	National Federation of State High School Associations
UNC	University of North Carolina
USC	University of Southern California

Thesis Introduction

Mouth guards (MGs) are generally accepted as appliances that reduce the incidence dental trauma during athletic activities (1–10). They originally surfaced around the 1930's in the dental literature as customized and protective mouthpieces for boxers (11). It was not until the 1940's that MGs became popular in other sports. Football adopted the use of MGs because there was convincing evidence that MGs reduced dental trauma during gameplay (12–14). In fact, the National Alliance Football Rules Committee made MGs mandatory for high school and junior college football in 1962. It was not until 1973 that the National Collegiate Athletic Association (NCAA) followed suit and made MGs mandatory for football. Today, the NCAA mandates MG use in four sports: football, ice hockey, lacrosse, and field hockey. The American Dental Association (ADA) and International Academy of Sports Dentistry (IASD) recommends MGs for eighteen sports, including basketball. The sports included in the recommendation are those which are considered “high risk” for dental trauma. In a systematic review and meta-analysis of MG use, athletes were found to be 1.6-1.9 times more likely to experience dental trauma if a MG was not used during the sport (6). It is not understood why the NCAA does not align itself more closely with the ADA and IASD, requiring MGs for more sports. There is a strong argument that basketball should be included in the NCAA's list of sports requiring MGs.

A study from the University of Southern California (USC) found that basketball had the highest incidence of dental trauma of NCAA sports in the study (5). They found men's and women's basketball had an overall incidence of 10.6 and 5.0 per 100 athlete seasons, respectively. In 2000, the USC women's basketball team made a policy of mandatory MG use, and the incidence dropped from 8.3 to 2.8 injuries per 100 athlete seasons. This finding was not statistically significant, but is highly suggestive of a protective effect for those who wear MGs

during basketball activities.. Only one other prospective study, from the University of North Carolina, demonstrates the effect of MGs in NCAA basketball (4). They found that MG users had an incidence of 0.12 per 1000 athlete exposures vs 0.62 for non-MG users. This was statistically significant. Although both of these studies express the incidence of trauma in different units, they follow a very similar pattern. If the findings from these two studies are extrapolated over the entire NCAA basketball athlete population (35,000 athletes), then the annual incidence of dental trauma would range from 2,200 to 2,600 traumatic dental events annually. This amounts to 6.2-7.4% of NCAA basketball athletes experiencing dental trauma every year. Other studies in high school athletes have also showed the incidence of orofacial and dental trauma in basketball athletes to be higher of other sports (10,15,16).

The evidence is quite clear that MGs can reduce dental trauma in basketball athletes (4,5). However, the compliance with recommendations to wear MGs is extremely low. Only 13% of NCAA men's basketball athletes were wearing MGs in a study from 2002 (4). In a survey of high school basketball/baseball/softball athletes, the most common reasons why MGs were not used were because it is not required (65%) and they could not breathe/talk well (61%) (17). Also, 87% of athletes reported their coach never talked about MGs and 64% of athletes reported the same about their parents. Another survey of high school athletes showed the most common reason to not wear a MG was that they were uncomfortable and easily forgotten (16).

The aim of this study is to identify the disconnect that is present between the evidence-based information on MG use in basketball athletes and the actual practice of MG use during basketball activities. A three-part study has been designed to accomplish this. Part One consists of a nationwide survey to all NCAA basketball programs to evaluate their procedures for MG use in their basketball athletes. Men's, Women's, Division I (DI), Division II (DII), and Division III (DIII) programs are included. The NCAA is divided into these divisions to provide different academic and athletic experiences for students. DI programs are athletics-intensive and can provide copious athletic scholarships to students. A significant emphasis on performance and

team contribution from athletes exists at DI schools. DIII schools do not award scholarships for athletes. This results in a more well-rounded approach to the overall college experience and an emphasis on academics. DII schools fall in between the two approaches of DI and DIII schools. There may be differences that exist between the divisions, regarding their dedication and resources to protect their basketball athletes from dental trauma. The null hypothesis to be tested is that there is not a significant difference in MG protocols for NCAA basketball programs throughout the United States.

Part Two consists of a prospective trial to test various modern MG materials in basketball athletes. Custom ethylene vinyl acetate (CustomEVA) MGs have been crowned the gold standard for dental trauma prevention(18). Traditional “boil-and-bite” MGs have been proven to be ineffective (19–22). There are several thermoplastic and rubber-based materials (silicone, polyolefin, polyurethane, polycaprolactone, etc.) being used in MGs today that are available over-the-counter (23). Their efficacy in reducing dental trauma *in vivo* is unknown, but they show promising *in vitro* results (23–25). The aim of Part Two is to obtain data on NCAA basketball athletes’ subjective experiences with four different MG materials. Regardless of how well a particular MG protects an athlete from dental trauma, the athlete will only benefit if the MG is consistently worn during basketball activities. The null hypothesis to be tested is that there is no difference between the athletes’ attitudes towards the four MGs.

Part Three is a review of the public health implications of MGs not being used in NCAA basketball. There are various long-term consequences of dental trauma. First, there are quantifiable direct and indirect financial consequences of traumatic dental injuries. Second, there are the various psychosocial consequences that are unique to each person and are impossible to quantify. This review will focus on the financial burden that the lack of MG use imposes on the NCAA basketball population, as well as highlight the national burden not wearing MGs places on basketball athletes of all ages.

MANUSCRIPT #1: CURRENT MOUTH GUARD PRACTICES IN NCAA BASKETBALL PROGRAMS

Introduction

Basketball is a sport associated with relatively high incidences of dental trauma (4,5). However, the NCAA does not require MGs during basketball activities. It does, however, have mandatory equipment rules in football, ice hockey, lacrosse, and field hockey for MG use during games. The National Federation of State High School Associations (NFSH) and International Academy of Sports Dentistry (IASD) recommends MGs for eighteen different sports (Table 1), including basketball. A meta-analysis by Knapik in 2007 showed that athletes who do not wear MGs are at a 1.6-1.9 times greater risk of dental trauma than those who do. Specifically in NCAA basketball, athletes are approximately 2-5 times less likely to experience dental trauma if a MG is worn during basketball activities (4,5). Despite the evidence supporting MG use in basketball, NCAA athletes and high school athletes playing basketball only wear MGs 13% and 4.5% of the time, respectively (2,4).

Table 1: Sports w/ recommended MG use by ADA and IASD

Football	Basketball	Rugby	Soccer	Volleyball	Equestrian
Martial Arts	Softball/Baseball	Track & Field	Ice Hockey	Field Hockey	Inline Skating
Lacrosse	Weightlifting	Racquetball	Boxing	Gymnastics	Water Polo

In a survey of high school basketball, softball, and baseball athletes, Collins *et. al.* demonstrated that athletes primarily do not wear MGs because they are not required and it is difficult to breathe/talk while wearing a MG. Hawn *et. al.* showed that in NCAA ice hockey, which has a mandatory MG rule by the NCAA, only 63% of athletes consistently wear MGs during games. These two studies highlight the fact that obtaining compliance with MG recommendations is a challenge, necessitating a significant overhaul in the approach to protect basketball athletes from dental trauma in the future. The purpose of this study is to evaluate current practices of NCAA basketball programs (Men's, Women's, DI-III) throughout the United States in order to make progressive and well-informed recommendations to better protect NCAA basketball athletes from dental trauma.

Materials and Methods

A Qualtrics® survey was developed to evaluate MG practices in NCAA basketball programs across the United States. IRB exemption was obtained (#19-0340) by the University of North Carolina IRB and Office of Human Research Ethics. The survey consisted of 12 questions, which are given below:

- 1) **What is the name of your college/university?**
- 2) **Provide your valid university email address.**
- 3) **What NCAA division is your college/university a member of?**
- 4) **Does your college/university have a Men's/Women's team, or both?**
- 5) **Do you think mouth guard use during basketball activities decreases the incidence of dental trauma in NCAA basketball athletes?**
- 6) **Are your NCAA basketball athletes required to wear mouth guards during basketball activities?**
- 7) **Is there a program to provide mouth guards to your NCAA basketball athletes?**

- 8) **Who is financially responsible for supplying mouth guards for your NCAA basketball athletes?**
- 9) **Who makes the mouth guards for your NCAA basketball athletes?**
- 10) **What type of mouth guard material is encouraged for your NCAA basketball athletes?**
- 11) **Are your NCAA basketball athletes informed on the risk and associated cost of dental trauma?**
- 12) **How many dental trauma incidents occurred to your NCAA basketball athletes in the last 12 months (Men& Women)?**

The survey was distributed via email to 1,105 NCAA basketball athletic trainers. E-mail addresses were manually acquired from the college/university athletic staff directory webpages. There were 9 NCAA colleges/universities not included in the study due to missing email information on the college/university athletics webpage, or because the webpage was not in English.

Statistical Methods

Upon completion of data collection, JMP® Pro V.14 was used to perform univariate and bivariate analysis. Significance level was set at $p < .05$.

Results

A response rate of 31% (348/1,105) was received from the nationwide survey distribution. See Figure 1 for national distribution of responses by location. No significant difference was found for the distribution of surveys received among the three NCAA Divisions. 39% were Division I, 37% Division II, and 24% Division III. 93% of athletic trainers have the opinion that MGs aid in the prevention of dental trauma during basketball activities. Only 2% of

programs require their athletes to wear MGs during basketball activities. 55% of programs do not inform their athletes on the potential risks and associated costs of dental trauma.

Overall, 45% of responding programs have a program to provide MGs to their athletes. However, Division I schools are statistically significantly more likely to have a MG program providing MGs to their athletes than Division II (OR=9.1, $p<.001$, CI 4.90-17.15) or Division III (OR=11.3, $p<.001$, CI 6.37-20.19) schools. No significant difference exists between DII and III schools. Division I schools are statistically significantly more likely to educate their basketball athletes on the risks of dental trauma than Division II (OR=2.2, $p=.006$, CI 1.26-3.84) and Division III (OR=1.8, $p=.019$, CI 1.10-2.93). No significant difference exists between DII and DIII schools. If the NCAA basketball athlete is financially responsible for providing a MG, then that school is statistically significantly less likely to have a MG program (OR=14.22, $p<.001$, CI 7.97-25.47). In regards to the types of MGs provided to NCAA basketball athletes, they are significantly more likely to receive a CustomEVA MG (OR=4.54, $p<.001$, CI 2.88-7.15) if the school has a MG program in effect.

NCAA Basketball athletic trainers also estimated the number of dental trauma incidences within the last 12 months for men's and women's teams. The men had a mean incidence of 1.26 traumatic events per school whereas the women had an incidence of 0.96. Although not a statistically significant difference, these frequencies are in agreement with those reported by Labella and Cohenca (4,5) when extrapolated over the entire NCAA basketball athlete population. No significant difference exists in the estimated number of dental traumas in schools with or without MG programs or dental trauma education.

Figure 1: Survey response distribution

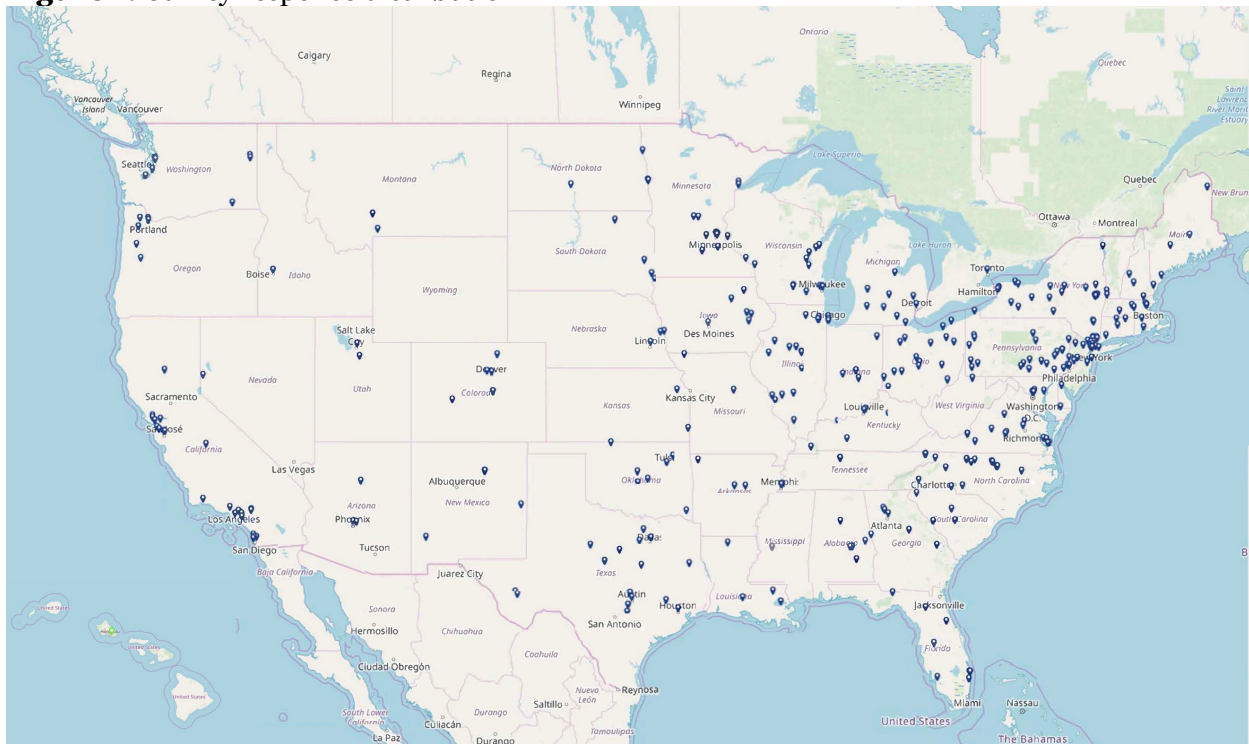


Table 2: Distribution of the 348 responses by division for questions 7 and 11.

	<u>MG Program?</u>		<u>Trauma Education?</u>	
	Yes	No	Yes	No
Div. I	103 (78%)**	29 (22%)	73 (55%)**	59 (45%)
Div. II	24 (28%)	62 (72%)	31 (36%)	55 (64%)
Div. III	31 (24%)	99 (76%)	53 (41%)	77 (59%)

** Indicate the statistically significant difference ($p < .05$) from DI to DII and DIII.

Discussion

NCAA basketball athletes are not required by NCAA regulations to wear MGs during basketball activities. Many programs do, however, recommend and provide MGs to their athletes. DI schools provide statistically significantly more MGs than DII or DIII schools. One explanation for this difference is the available resources to DI programs vs. DII and DIII. DI basketball is a largely profitable and self-sustainable sport. According to the NCAA DI basketball is responsible for generating over \$1 billion in annual revenue. Of that, approximately 5% and

3% get distributed to DII and DIII schools through annual budgets to support the programs, respectively.

The available financial resources to a basketball program also likely explains the type or MG provided to athletes and who makes the MG. DI schools had significantly more MG programs that provided CustomEVA MGs, which tend to be more expensive than stock options. This likely also caused the result DI programs also had more MGs made by trained professionals (Dentist/Athletic Trainer), because EVA MGs are generally fabricated by a professional.

Although DI schools generally have more MG programs for their athletes and provide better quality MGs for them, the athletic trainers estimates on incidence of dental trauma was not statistically significantly lower than DII or DIII schools. There could be a few explanations for this result. First, the athletes might not be wearing their MGs. This further emphasizes the point that athletes do not wear MGs because they are not required or they are uncomfortable (11). Another reason could be the intensity level of the game. DI athletes are generally bigger, faster, stronger, and play more hours per week than DII and DIII. Further investigation needs to be pursued to evaluate if there are different levels of traumatic forces experienced in DI, DII, or DIII basketball.

The overall level of education basketball athletes receive regarding dental trauma is not sufficient. Only 45% of athletes receive education on dental trauma, and this percentage drops to 38% if DI schools are excluded. If athletes are not being required to wear MGs by the NCAA, the programs should provide better education to their athletes so they can make an informed decision on how to approach MG use during basketball activities.

Conclusion

Division I NCAA basketball programs provide appropriate MGs to their athletes and educate them on the risks of dental trauma, more so than Division II or Division III programs .

In order to better protect all NCAA basketball athletes, the NCAA should consider implementing a mandatory MG rule and providing MGs to all of their basketball athletes.

MANUSCRIPT #2: SUBJECTIVE ANALYSIS ATHLETES OF MOUTH GUARDS BY NCAA BASKETBALL ATHLETES: A PILOT TRIAL

Introduction

The main reasons consistently reported by basketball athletes for not wearing MGs is because they are uncomfortable or difficult to breathe while wearing them (17,26–29). Therefore, many basketball athletes opt not to wear MGs during basketball activities—approximately less than 15% of them actually do wear MGs (2,4,17). This results in the incidence of dental trauma during basketball to be uncharacteristically high when compared with other contact sports, even though basketball is considered a non-contact sport (5). A meta-analysis showed MGs decrease the incidence of dental trauma in all athletes by 1.6 to 1.9 times. If basketball is isolated from all other sports, the risk of dental trauma decreases by 2.0 to 5.5 times when a MG is worn, depending on the study (4,5,9).

Custom ethylene vinyl acetate (CustomEVA) MGs have been crowned as the gold-standard for maximum comfort and protection in sports dentistry (18). They can either be pressure-formed or vacuum-formed. Laminated pressure-formed EVA MGs, allow for a greater degree of precision and customization in the MG thickness when compared to the vacuum-formed method. When vacuum-formed, the MG can be reduced by 25-50% of the original EVA sheet thickness (29). Self-adapted MGs, commonly known as “boil-and-bite” MGs, have been shown to be less comfortable and less protective than CustomEVA MGs (30). Because of their low cost, availability at local sporting goods stores, and no need to visit a dentist, the majority of MGs used are of the self-adapted type.

MG materials have evolved significantly since their inception in the 1890's as gutta percha strips that were fitted by a London dentist, Woolf Krause, over the central incisors of

boxers (11). In the 1930's, dentists began to collaborate on ways to fabricate custom MGs of wax and rubber for boxers (6). In 1960, the ADA began to endorse latex MGs for football athletes, and in 1973, the NCAA mandated MG use for football players. Since then, the majority of MGs available are made of EVA, polyvinylchloride (PVC), acrylic resin, polyurethane (PU) or latex rubber (19,29,31). Today, there are many innovative companies making advancements with MG materials for enhanced protection. According to a study by Absolute Reports®, the MG market in the United States had a gross revenue of \$170 million in 2019, and is projected to be \$240 million by 2024. MG producers are combining materials, adding impact sensors, body temperature sensors, periodontal disease sensors, and pushing the limits on functional thickness of the materials (23,32). Unfortunately, there is not a standardized model for which these new MGs can be tested and graded by for their ability to prevent dental trauma. This leaves the market vulnerable to unsubstantiated or biased claims about the protective capabilities of the MGs.

Regardless of a MG's protective capabilities, the device will only benefit the athlete if it is actually worn during sporting activities. Many recommendations have been made to athletic organizations, like the NCAA and the NFSH, to make MGs a requirement for basketball because of the high incidence of dental trauma. The main reasons basketball athletes do not wear MGs are because they are not required and uncomfortable to wear. If a basketball athlete has had a previous trauma, they are 2.76 times more likely to wear a MG. Cost and decreased athlete performance are also commonly cited roadblocks to universal MG implementation in basketball (17,33–35). Some recent studies have showed newer self-adapted MGs to be nearly as effective as EVA MGs *in vitro* (23–25). To supply the entire NCAA basketball athlete population with CustomEVA MGs or self-adapting MGs would cost \$2M or \$875k, respectively. It would be very reasonable for the NCAA to mandate MG use if a self-adapted MG available is as comfortable, inexpensive, and as protective as CustomEVA MGs.

The purpose of this study was to obtain subjective feedback from NCAA basketball athletes on three commercially available MGs (Sisu Aero Guard, GameOn Mouthguard, and Shock Doctor Basketball Superfit) and compare them to their experience with 3mm CustomEVA MGs. These three MGs were chosen because of their relative thinness (Table 3) when compared to the standard CustomEVA MG (Table 1), which may result in better comfort. The null hypothesis to be tested is no difference exists between NCAA basketball athlete subjective experience with the 4 different MGs.

Table 3: Characteristics of MGs in the study.

	MG Type	Material	Material Thickness	Cost	Warranty (Maximum)
CustomEVA	Custom	Ethylene Vinyl Acetate	3.0 mm	\$99.99	None
Sisu Aero Guard	Self-Adapted	Ethylene Vinyl Acetate + Polycaprolactone Copolymer	1.6 mm	\$24.99	\$35,000
GameOn	Self-Adapted	All-Polyolefin propylene-ethylene copolymer (PEC)	2.0 mm	\$24.99	\$10,000
Shock Doctor Superfit	Self-Adapted	Ethylene Vinyl Acetate with Polyurethane Copolymer	2.0 mm	\$19.99	\$10,000

Materials and Methods

Ten men's basketball athletes from the University of North Carolina Chapel Hill were recruited to participate in the study. IRB approval (#19-0324) was obtained from the University of North Carolina IRB and Office of Human Research Ethics, informed consent was reviewed and signed by all 10 participants. Each athlete was given one of each of the following MGs: CustomEVA, Sisu Aero Guard (Akervall Technologies Inc., Saline, MI), GameOn Mouthguard (GameOn® Mouthguards, Louisville, KY), and Shock Doctor Superfit Basketball Mouthguard (Shock Doctor Inc., Fountain Valley, CA). The athletes were all instructed to wear a MG for one week while performing basketball activities, and fill out a Qualtrics® online survey regarding

their subjective experience with that particular MG. This cycle was repeated for four weeks. The survey aimed to obtain subjective feedback on the MG fabrication process, overall comfort, ability to breathe, ability to communicate, ability to drink, ability to focus on basketball, and then give an overall score for the MGs. See Appendix for full survey. The rating scale was 0-100 for all questions.

To fabricate the CustomEVA MGs, dental impressions were made using alginate-substitute impression material (Penta™ Quick VPS, 3M, Minneapolis, MN) of the maxillary arch were made for each athlete and then poured up in ISO type III microstone (WhipMix®, Louisville, KY). Casts were trimmed and used to make vacuum-formed EVA MGs from 3mm clear EVA blank sheets (Great Lakes Dental Technologies, Tonawanda, NY). The CustomEVA MGs were trimmed to the guidelines published by Lloyd *et. al.* for the International Sports Dentistry Workshop (distal of 1st molar to 1st molar, extends at least to gingival margins, 3mm facially/occlusally, 2mm palatally), and then polished with pumice to create smooth and comfortable edges. For the other three MGs, instructions were given to the athletes on how to fit them, and were told to ask if they had questions. Reminders were sent to the athletes the day before surveys were due, the day the surveys were due, and up to 2 days after the surveys were due so accurate and complete data could be obtained.

Statistical Methods

Upon completion of data collection, JMP® Pro V.14 was used to perform descriptive statistics and paired t-test analysis. Significance level was set at $p < .05$.

Results

Ten out of ten (100%) of the surveys were fully completed and submitted for the CustomEVA, GameOn, and Shock Doctor groups. One athlete was concerned about using the Sisu Aero Guard with Invisalign attachments, and never reached out to the research team to aid

with fitting the MG. Therefore, the Sisu group had a nine out of ten (90%) response rate.

Consolidated mean scores and standard deviations can be seen in Table 4. The MG with the highest mean overall score was the CustomEVA (83.8, SD=13.9), which was significantly greater than Sisu ($p=.02$), GameOn($p=.02$), and Shock Doctor ($p=.01$). CustomEVA also had the highest mean score for comfort (74.8, SD=16.6), fitting process, ability to breathe, drink, communicate, and focus while wearing the MG when compared to the other three MGs. No statistically significant difference between MGs was found for the ability to drink while wearing the MGs. The CustomEVA was statistically significantly more comfortable than the Shock Doctor MG ($p=.01$). The CustomEVA MGs received a mean score that was statistically significantly greater than the mean score of GameOn MGs ($p=.03$) for the fitting process of the MGs. For ability to breathe while wearing the MGs, only CustomEVA had a statistically significant mean score difference when compared with GameOn MGs ($p=.04$). No statistically significant differences exist in the athletes' ability to drink while wearing the four various MGs. For the athletes' ability to communicate while wearing the MGs, only the CustomEVA showed a statistically significant difference of mean scores over the Shock Doctor MG ($p=.01$). For the athletes' ability to focus on playing basketball while wearing the MGs, only the CustomEVA showed a statistically significant difference of mean scores over the Shock Doctor MG ($p=.04$). None of the three self-adapted MGs performed significantly better than any other MG in all of the categories tested.

Table 4: Mean scores (standard deviation) for the four MGs tested

	CustomEVA	Sisu	GameOn	Shock Doctor
Comfort	74.8 (15.8)**	60.5 (23.3)	65.3 (12.5)	58.3 (16.7)*
Fitting Process	74 (16.7)**	61 (14.5)	56.4 (16.3)*	67.6 (13.1)
Breathe	82 (12.8)**	72.2 (15.1)	70.5 (14.4)*	68.7 (19.6)
Drink	74 (22.1)	70.7 (21.2)	74 (13.5)	63.7 (23.2)
Communicate	67.9 (25.06)**	60.8 (17.0)	62.0 (18.9)	51.1 (20.2)*
Focus on B-Ball	86.6 (16.0)	75.1 (18.4)	72.6 (23.4)	72.5 (16.9)
Overall Score	83.8 (13.2)**	64.7 (15.8)*	66.5 (15.5)*	60.2 (16.0)*

Value** Indicates a statistically significantly different ($p<.05$) higher mean score than value*

Discussion

To our knowledge, this is the first study to obtain subjective evaluations from NCAA basketball athletes on commercially available and CustomEVA MGs. Overall, the NCAA basketball athletes preferred the CustomEVA MG, despite it being the thickest MG tested in this study (see Table 3). This may be explained by the lack of excess material used for CustomEVA MGs. They are specifically trimmed to only cover exactly what is required for minimum necessary protection, according to Lloyd *et. al.*(18). Self-adapted MGs are meant to fit a wide-range of mouth types, likely making it less comfortable for those who do not have a “standard” mouth size and shape. Similar performed in other athletes also found a preference towards CustomEVA MGs when compared with the self-adapted type (27,36). The main complaints of discomfort with the self-adapted MGs were gingival irritation and looseness, which may be a result of excess material needed to fit a wide range of athletes. The current study did not evaluate these specific parameters.

A particularly important question asked in this study was on the athletes’ ability to focus on playing basketball while wearing the MGs. The only statistically significant difference was between CustomEVA and Shock Doctor, favoring CustomEVA. Of the thirty nine surveys recorded, only six reported a perfect “ability to focus” score while playing basketball as if they weren’t wearing a MG at all. Four were for CustomEVA, one for GameOn, and one for Sisu. This indicates that the large majority (85%) of the athletes were negatively affected or distracted while wearing the MG and playing basketball to some degree. Interestingly, about 13% of NCAA basketball athletes regularly wear MGs, and about 15% of the responses in this study stated that their focus was not affected while wearing a particular MG. We did not ask if the athletes regularly wear MGs during basketball activities, which could explain the percentage of athletes who responded with a perfectly normal ability to focus while wearing the MGs.

The nature of the study was aimed for minimal contact time with the athletes due limited access and busy schedule of UNC basketball athletes. One downside this created was the

inability to confirm that the self-adapted MGs were fit properly by the athletes. They were all given detailed fitting instructions, but none of the athletes reached out with questions or concerns about the fit of any of the MGs. This means that either they all fit the MGs perfectly, which is unlikely, or the athletes had issues that were not addressed. In future studies, it would be beneficial to train the athletic training staff on how the MGs are supposed to fit, allowing for better supervision over the athletes as they use the MGs. One of the benefits of the self-adapted MGs used in this study (Sisu, GameOn, Shock Doctor Superfit) is that they can be remolded multiple times to achieve the ideal fit. Assistance from a trained professional, i.e. an athletic trainer, could potentially achieve a fit closer to that of CustomEVA MGs. Future studies are needed to confirm this.

If self-adapting MGs can be as comfortable and wearable as CustomEVA MGs, then there is a strong argument for universal MG use in basketball athletes, particularly in the NCAA, where the incidence of dental trauma is very high. A MG with a comfortably tight fit, like a CustomEVA MG, allows for the athlete to have greater confidence in speaking, running, drinking, and playing basketball. Otherwise, the athlete needs to consciously hold the MG in place with their tongue, cheeks, and mandibular teeth. The cost and accessibility of self-adapting MGs is far more convenient for basketball athletes than CustomEVA MGs. Even though CustomEVA MGs show to be more protective than the majority of self-adapted MGs, there is enough evidence to recommend polyolefin or EVA copolymers MGs to those who cannot afford CustomEVA MGs. According to other studies, having a polyolefin or EVA copolymer MG will provide at least more protection than no MG, and has the potential to be as comfortable as CustomEVA according to the results of this study (23–25). Further research is necessary, preferably with a standardized *in vitro* model, for the protection capabilities of these MGs and for specific parameters that makes a MG comfortable or not.

Conclusion

NCAA basketball athletes prefer CustomEVA MGs over the Sisu Aero Guard, GameOn MG, and Shock Doctor Superfit Basketball MG in regards to their overall subjective experience with the MGs. However, the self-adapted MGs may be a quality alternative to many basketball athletes, especially if they are not wearing a MG and do not plan on having a CustomEVA MG made

MANUSCRIPT #3: PUBLIC HEALTH IMPLICATIONS OF NOT MANDATING MOUTH GUARDS IN NCAA BASKETBALL

Introduction

Basketball is the most popular team sport in the United States with over 23 million annual participants, according to the Sports and Fitness Industry Association. It is also generally ranked as the second or third most popular in the world (#1:soccer, #2/3: cricket). NCAA basketball and the National Basketball Association (NBA) have annual revenues that approximate \$1 billion and \$8 billion, respectively. Needless to say, basketball is a powerhouse of an industry within the United States and worldwide. Many epidemiological studies exist on various age groups of basketball athletes to estimate the incidence of bodily injuries during basketball activities. When compared with other “non-contact” sports (and some “contact” sports), basketball is consistently shown to have high rates of injuries. Ironically, the most common mode of injury (46% of injuries) in basketball is player-to-player contact (37).

Medical and dental professionals have a responsibility to evaluate research and construct injury prevention mechanisms for athletes. In 1992, van Mechelen *et. al.* published the four steps in the “sequence of prevention”(38). Steps 1 and 2 focus on incidence and etiology of a specific injury, respectively. Step 3 is to introduce measures that should reduce the incidence or risk of the said injury. The 4th and final step is to go back and evaluate if intervention actually decreased the incidence of trauma. In a segmented way, Mechelen’s sequence of prevention has been completed for the prevention of dental trauma in NCAA basketball athletes, with the intervention being mouth guard (MG) use. A couple of studies show the incidence of dental trauma with and without MGs in NCAA basketball athletes (4,5). The NCAA, however, does not mandate MG use in basketball athletes, which causes the incidence of

dental trauma to remain high. This review aims to: 1) Magnify the fact that MG use should be universal and required by the NCAA for basketball, and 2) Illustrate the current public health problem of dental trauma in basketball athletes of all ages throughout the United States.

Dental Trauma in Basketball

Incidence of sports injuries are often expressed in many different units. Athlete seasons, athlete exposures (AEs), and hours of participation are commonly seen in the sports-related dental trauma literature. See table 5 for AEs for NBA, NCAA, and high school for comparison. In NCAA basketball, the overall incidence of injuries for men and women is 8.1-8.9 and 6.1-6.9 injuries per 1000 AEs, respectively. This amounts to approximately 27,000 total injuries per year (37,39–41). It has also been shown that injuries happen at a higher rate in both men’s and women’s basketball during competitive gameplay vs. practice (37,40,42). Injuries occur at approximately 4 injuries/1000 AEs during practice for men and women. During competitive gameplay, men experience 9.9 injuries/1000 AEs and women experience 7.7 injuries/1000 AEs (42). No study directly measures what percentage of the total NCAA basketball injuries are dental related, likely due to the fact that not all dental injuries result in time lost for the athlete and non-specific reporting guidelines for dental injuries. Dick *et. al.* reports that head and neck injuries account for 11.2% to 13.9% of injuries in NCAA basketball practice and games, respectively.

Table 5: Comparison of approximate AEs by level of competition.

	Games per Year	Practices per Year	AE per Year	Number of Athletes	Total AEs
NCAA	25 to 35	100	125-135	35,000	4.55M
High School	25 to 35	80	105-115	1M	110M
NBA	82 to 98	25	102-123	500	82,000

Two epidemiological studies have been published that evaluate the incidence of dental trauma in NCAA basketball athletes. Cohenca *et. al.* compared the incidence and severity of dental injuries between various men's and women's sports (basketball, football, baseball, track and field, water polo, and volleyball) from 1996-2005 and expressed the incidence by injuries per 100 athlete seasons (AS). The men's basketball team had the highest incidence of dental trauma at 10.6 injuries/100 AS. The women's team averaged 5.0 injuries/100 AS, but had a mandatory MG rule implemented halfway through the observation period. During the first half, the women's team had an incidence rate of 8.3 injuries/100 AS, which then dropped to 3.0 injuries/100 AS after the MG rule. This drop in the incidence was not statistically significant, likely because of the relatively small sample sizes, but is highly suggestive of the protective function of MGs in NCAA women's basketball. They also showed that the most common dental injury was a non-complicated crown fracture, but that 65-75% of dental injuries fell into the "moderate to severe" category (complicated crown fracture, subluxation, crown-root fracture, root fracture, luxation, and avulsion) (5). Labella *et. al.* performed a prospective surveillance of 50 Division I NCAA basketball programs to evaluate dental injuries and concussions for MG and non-MG users, expressed by injuries per 1000 AEs. They found the incidence of dental trauma dropped from 0.67 to 0.12 injuries per 1000 AEs if a MG is used, a statistically significant finding(4). The number of dentist referrals significantly dropped from 0.72 to 0.00 referrals per 1000 AEs. It should also be noted that all of the MG users had custom-made MGs from a dental professional. Approximately 40% of the dental injuries were luxations, whereas over 50% were "tooth fractures". This nomenclature is not specific enough to compare with the scale of "mild-moderate-severe" reported in the Cohenca study. The NCAA injury surveillance system needs to consider traumatic dental injuries more attentively to allow for more comprehensive understanding of the dental trauma epidemiology in NCAA basketball athletes.

Although Labella expressed their findings in AEs and Cohenca in AS, they are in very close agreement with one another. If these figures of Cohenca and Labella are representative of

the entire NCAA population, then the overall incidence of dental trauma would be 9.4% (3,307 dental traumas) to 8.6% (3,015 dental traumas), respectively. The survey from Part One: Current Mouth Guard Practices in NCAA Basketball programs asked athletic trainers of basketball programs to estimate the incidence of traumatic dental injuries over the previous twelve months. Men's teams had a mean incidence of 1.26/team, and women's teams had a mean incidence of 0.96/team. Knowing that there are about 15 athletes per NCAA basketball team, these numbers can also be generalized over the entire NCAA basketball population to find an incidence of 7.4% (2,594 dental traumas) per year. Athletic trainers may be biased and may have underreported the amount of dental traumas their program had, whether it be consciously or subconsciously, because it makes them personally look better if their athletes have less injuries. This could explain the slightly lower incidence of dental trauma found in the survey results compared to Cohenca and Labella. Given the best evidence available today, the incidence of dental trauma in a given NCAA basketball athlete is approximately 7.4-9.4% per year (Table 5).

Table 6: NCAA Basketball dental trauma incidence.

	Sample Incidence	NCAA Population Incidence
Cohenca <i>et. al.</i> 2007	10.6(M) and 8.3(W) / 100 AS	3,307 (9.4%)
Labella <i>et. al.</i> 2002	.67(M) / 1000 AE	3,015 (8.6%)
Goglia, Manuscript #1	1.26(M) and 0.96(W) / 15 athletes	2,590 (7.4%)

Mouth Guard Use in Basketball

The usage of MGs during basketball activities is low, despite recommendations from the ADA and IASD. One survey found 12.3% of high school basketball/ softball/baseball athletes wear a MG (17). Another study of NCAA men's basketball athletes found a 13% MG usage rate (4). In the survey from Part One, 93% of athletic trainers reported that they think MGs reduce

the incidence of dental trauma, but only 2% of programs require MGs for their athletes. One more survey of basketball athletes found that 95% of the athletes think MGs are protective, but only 6% of those same athletes actually wore a MG (43). A consistent finding that increases the likelihood, by 2.7 times, of basketball athletes wearing a MG is if they have had a previous dental trauma (44).

Several studies have attempted to characterize why basketball athletes do not wear MGs. The main reasons that MGs are not worn by athletes in general is because they are not required, they are uncomfortable, and they cause difficulty in breathing/speaking when worn (17,43). Many studies have evaluated ventilation and aerobic respiration on athletes wearing MGs, and there does not seem to be a negative effect (45–47). People surrounding athletes, parents/dentists/coaches/training staff, are thought to also have influence over the use of MGs in athletes, and lack a perceived need for MGs in basketball (28,33,34,48). A study by Maestrello *et. al.* showed 58% of general dentists thought that MGs should be used during basketball (33). It is unclear why many people, including dental professionals, do not think MGs are a necessity for basketball athletes. Possibly, it is the “non-contact sport” label that basketball receives. Dental professionals, athletic trainers, parents, and coaches need to become better educated on the risks of dental trauma in basketball, so the athletes can ultimately be informed on proper MG use during basketball activities.

There are three main types of recognized MGs on the market today: stock, self-adapted (boil & bite), and custom. It has been made clear that custom ethylene vinyl acetate MGs offer superior protection when compared to stock or self-adapted MGs, and athletes generally find the custom MGs more comfortable (7,19,49–51). Custom MGs only have about 25-50% thinning whereas self-adapted MGs have about 70-99% thinning (29). In 2017, Lloyd *et. al.* published a report from the International Sports Dentistry Workshop with guidelines for CustomEVA MGs. They should extend from the distal of the left maxillary first molar to the distal of the right maxillary first molar, be 3mm labially and occlusally, and be 2mm palatally (18). Other MG

materials, like polyolefin and EVA/polycaprolactone combinations, are showing impact reduction results similar to EVA *in vitro* (23,24). However, more publications with similar findings are needed to validate these results. Based on current evidence, basketball athletes should be wearing MGs in accordance with Lloyd *et. al.* for maximum protection and comfort.

Financial Benefit of MGs

Estimating the cumulative cost of a dental trauma event over a patient's lifetime is a challenging task. There are direct costs of dental treatment relative to the severity of the injury, indirect costs of missing work and commuting to dental appointments, and immeasurable psychosocial effects from trauma. Direct costs of dental treatment can range from a few hundred dollars to treat an uncomplicated crown fracture, to tens of thousands of dollars for treating an avulsed tooth. A study from 1991 estimated the lifetime cost of an avulsed tooth to be \$5,000-\$20,000 (52). When adjusting for inflation, this estimate would equate to \$9,500-\$38,000 in 2020.

Knowing the direct costs of dental trauma to NCAA basketball athletes on an annual basis would require a well-designed study organized by the NCAA and their injury surveillance program. This data is not available today, so estimating these figures is difficult, but not impossible. Two studies, by Labella and Cohenca, characterize the severity of dental trauma in NCAA athletes. However, neither of the two studies follow the complete terminology of the International Association of Dental Traumatology guidelines for dental trauma. Nonetheless, 24%-45% of the injuries in these two studies fall into Cohenca's "severe" category (avulsions, luxations, root fractures). According to Andreasen, the range of pulpal necrosis for these injuries would be 25%-100% in mature teeth (53). Pulpal complications lead to more expensive dental treatments, which also lead to more dental office visits and greater indirect costs of treatment. Based off of the incidence of dental trauma in NCAA basketball athletes, as discussed previously,

there may be between 750-1,350 complicated/severe dental traumas annually. This would aggregate to \$4.5M-\$8.0M of direct lifetime dental costs to NCAA basketball athletes annually.

Indirect costs are unique to each individual, comprising of transportation costs, time lost from missing work, childcare, etc. A Danish study in 1998 found complicated traumas resulted in an average of 16.4 office visits versus 9.2 office visits for uncomplicated trauma (54). Another study finds that the most significant indirect cost of managing dental trauma is loss of production at work, which is highly individualistic but averaged approximately \$125 per visit (55). Over 16 visits, from a complicated trauma, indirect costs of treatment could amount to an additional \$2,000. This would add \$1.5M-\$2.5M to the direct costs of 750-1,350 complicated dental traumas that is expected annually in NCAA basketball athletes. The total of direct and indirect costs of dental trauma in NCAA basketball athletes is \$6.0M-\$10.5M. Conservative estimations were used while calculating this total, so it very well may be an underestimation of the true costs.

A significant portion of the costs will be after the student athlete has left the college/university they played basketball for. According to the NCAA, less than 2% of their athletes play professionally. That indicates 98% of the athletes who experience dental trauma as an NCAA basketball athlete will not have the salary of a professional basketball player to unreservedly cover the costs. The total cost to provide the entire NCAA basketball athlete population (35,000 athletes) with CustomEVA MGs would be about \$2M in raw material costs and lab fees. Athletic trainers could easily be trained to make the impressions required for MG fabrication. Also, not all athletes would need a new MG every year, which would reduce the annual cost of providing MGs. With NCAA basketball being a \$1B industry, supplying MGs to their athletes would cost .2% of their budget. This action would prevent unnecessary future costs and treatments for the athletes.

Discussion

NCAA Basketball is an example to all basketball athletes within the United States and around the world. There were over 100 million live streams from the 2019 NCAA men's basketball tournament (March Madness) in the United States. Whatever NCAA Basketball does, people watch and take note. There are approximately 26 million people who play basketball regularly in the United States. Even if the incidence of dental trauma for the general public is less than that of NCAA athletes, there could be about \$2.0B of direct costs for basketball-related dental trauma. Indirect costs would add approximately \$780M to that total. The current practices of MG education and policy implementation are insufficient, given the incidence and severity of dental trauma in basketball today. Studies have showed that MGs will not be worn unless they are required by rule (17). It is time for the NCAA to put a mandatory equipment rule in place for NCAA basketball (men and women)—for MGs. It is a simple and cost effective solution that should reduce the incidence of dental trauma in basketball athletes. A paradigm shift is necessary, and long overdue, within the sport of basketball regarding MGs. MGs should be required to play, for the sake of NCAA athletes, NBA athletes, and those within the general public who enjoy the game of basketball.

APPENDIX A: SURVEYS

Part One Survey: National NCAA Basketball Program Survey



What is the name of your college/university (please be specific)?

Provide your valid university email address (for quality control only--no additional emails will be sent):

What NCAA division is your college/university a member of?

Div. I

Div. II

Div. III

Does your college/university have men's, women's, or both NCAA basketball teams?

Men's

Women's

Both

Do you think mouthguard use during basketball activities decreases the incidence of dental trauma in NCAA basketball athletes?

Yes

No

Are your NCAA basketball athletes required to wear mouthguards during basketball activities?

Yes

No

Is there a program to provide mouthguards to your NCAA basketball athletes?

Yes

No

Who is financially responsible for supplying mouthguards for your NCAA basketball athletes?

The College/University

The Athletes Themselves

Dental Professional

Nobody

Who makes the mouthguards for your NCAA basketball athletes?

Dentist

Athletic Training Staff

The Athletes Themselves

Nobody Does

What type of mouthguard material is encouraged for your NCAA basketball athletes?

Custom/Professional (EVA)

Over-the-Counter (Boil & Bite)

Other (Please Specify)

Are your NCAA basketball athletes informed on the risk and associated cost of dental trauma?

Yes

No

How many dental trauma incidents occurred to your NCAA basketball athletes in the last 12 months?

Men's



Women's



Part Two Survey: Subjective Analysis of MG Survey (same survey for all four MG groups)
Random scores selected to illustrate the sliding scale (0-100)



How Comfortable is the Mouthguard (MG)?

PAINFUL

PERFECT



How Was the Process of Fitting/Making This MG?

EXTREMELY INCONVENIENT

FAST & EASY



Were You Able to Breathe While Wearing the MG?

NOT AT ALL

PERFECTLY



Were You Able to Drink While Wearing the MG?

NOT AT ALL

PERFECTLY



Could You Communicate While Wearing the MG?

NOT AT ALL

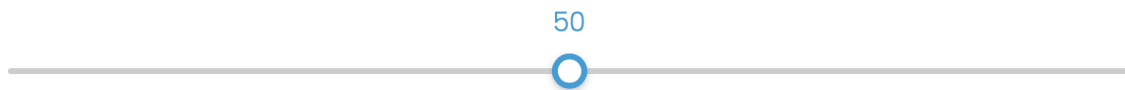
PERFECTLY



Could You Focus on Playing Basketball While Wearing the MG?

COULDN'T FOCUS ON BASKETBALL

PERFECTLY



Overall MG Score

WORST MG EVER

BEST MG EVER



APPENDIX B: IRB APPROVAL LETTERS



THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

OFFICE OF HUMAN RESEARCH ETHICS

720 Martin Luther King, Jr. Blvd.
Bldg. 385, 2nd Floor
CB #7097
Chapel Hill, NC 27599-7097
(919) 966-3113
Web site: ohre.unc.edu
Federalwide Assurance (FWA) #4801

To: James Goglia and Ibrahim Duqum
Endodontics

From: Office of Human Research Ethics

Date: 2/18/2019

RE: Notice of IRB Exemption

Exemption Category: 2. Survey, interview, public observation

Study #: 19-0340

Study Title: Mouthguards in NCAA Programs--Part One

This submission has been reviewed by the Office of Human Research Ethics and was determined to be exempt from further review according to the regulatory category cited above under 45 CFR 46.101(b).

Study Description:

Purpose: To evaluate current mouthguard practices in NCAA basketball programs across the United States. Currently, the NCAA does not mandate mouthguard use for NCAA basketball (Men's and Women's).

Participants: NCAA Athletic Trainers

Procedures (methods): A Qualtrics survey will be sent to every NCAA basketball program in the United States (1,089 men's programs/1,184 women's programs) to evaluate current mouthguard recommendations and practices.

Study Regulatory and other findings:

The IRB conducted a limited review and determined that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Investigator's Responsibilities:

If your study protocol changes in such a way that exempt status would no longer apply, you should contact the above IRB before making the changes. There is no need to inform the IRB about changes in study personnel. However, be aware that you are responsible for ensuring that all members of the research team who interact with subjects or their identifiable data complete the required human subjects training, typically completing the relevant CITI modules.

The IRB will maintain records for this study for 3 years, at which time you will be contacted about the status of the study.

page 1 of 2

The current data security level determination is Level I. Any changes in the data security level need to be discussed with the relevant IT official. If data security level II and III, consult with your IT official to develop a data security plan. Data security is ultimately the responsibility of the Principal Investigator.

Please be aware that approval may still be required from other relevant authorities or "gatekeepers" (e.g., school principals, facility directors, custodians of records), even though the project has determined to be exempt. .

CC:
Siggi Saemundsson, Pediatric Dentistry
Peter Tawil, Endodontics



THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

OFFICE OF HUMAN RESEARCH ETHICS

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Web site: ohre.unc.edu
Federalwide Assurance (FWA) #4801

To: James Goglia and Ibrahim Duqum
Endodontics

From: Biomedical IRB

Approval Date: 3/07/2019

UNC Administrative Review Due Date: 3/06/2020

RE: Notice of IRB Approval by Expedited Review (under 45 CFR 46.110)

Submission Type: Initial

Expedited Category: 4.Noninvasive clinical data,7.Surveys/interviews/focus groups

Study #: 19-0324

Study Title: Mouthguards in NCAA Basketball Programs--Part Three

This submission, 240659, has been approved by the IRB. It has been determined that the risk involved in this research is no more than minimal. **This research requires annual UNC administrative review.** Under the revised 'Common Rule' of 2018, this study does not require continuing review and IRB approval will not expire.

Study Description:

Purpose: Basketball has a relatively high incidence of dental trauma when compared with other sports. This is largely due to the lack of compliance with evidence-based recommendations to wear mouth guards during gameplay. The purpose of this study is to evaluate why the evidence of mouth guards reducing trauma in basketball athletes has not translated into consistent use of mouth guards during basketball activities.

Participants: NCAA basketball athletes of local NCAA basketball programs

Procedures (methods): A three-part NCAA-focused study was created. Part One is a nationwide survey of all NCAA basketball programs' mouth guard practices. Part Two is an *in vitro* study using a novel outcome-based TrueJaw™ trauma model to evaluate modern mouth guard materials by Sisu™ and GameOn™. Part Three is composed of a prospective NCAA basketball athlete trial to acquire subjective data on the mouth guards tested in Part Two.

Investigator's Responsibilities:

As an institution accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP), all research approved under expedited procedures must receive an administrative review at least annually. It is the Principal Investigator's responsibility to submit a UNC administrative review report as requested by the IRB. Failure to respond to this request is considered non-compliance with IRB requirements and University policies.

Your approved consent forms and other documents are available online at
http://apps.research.unc.edu/irb/index.cfm?event=home.dashboard_irbStudyManagement&irb_id=19-0324.

You are required to obtain IRB approval for any changes to any aspect of this study before they can be

page 1 of 2

implemented.

New Safety Information should be reported to the IRB, in IRBIS, as per [OHRE SOP 1401](#).

Please be aware that additional approvals may still be required from other relevant authorities or "gatekeepers" (e.g., school principals, facility directors, custodians of records).

The current data security level determination is Level II. Any changes in the data security level need to be discussed with the relevant IT official. If data security level II and III, consult with your IT official to develop a data security plan. Data security is ultimately the responsibility of the Principal Investigator.

This study was reviewed in accordance with federal regulations governing human subjects research, including those found at 45 CFR 46 (Common Rule), 45 CFR 164 (HIPAA), 21 CFR 50 & 56 (FDA), and 40 CFR 26 (EPA), where applicable.

CC:

Siggi Saemundsson, Pediatric Dentistry
Peter Tawil, Endodontics



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Federalwide Assurance (FWA) #4801

To: James Goglia and Ibrahim Duqum
Endodontics

From: Biomedical IRB

Approval Date: 10/11/2019

UNC Administrative Review Due Date: 10/06/2020

RE: Notice of IRB Approval by Expedited Review (under 45 CFR 46.110)

Submission Type: Modification

Expedited Category: 4.Noninvasive clinical data,7.Surveys/interviews/focus groups,Minor Change to
Previously Approved Research

Study #: 19-0324

Study Title: Mouthguards in NCAA Basketball Programs--Part Three

This submission, Reference ID 255621, has been approved by the IRB. It has been determined that the risk involved in this modification is no more than minimal. Unless otherwise noted, regulatory and other findings made previously for this study continue to be applicable.

Submission Description:

A fourth group of mouthguards to be tested is going to be added to the study. Therefore, the study will run for one additional week and requires one additional survey. All together, the athletes will wear one of four mouthguards (Sisu, GameOn, Custom EVA, Shock Doctor) per week for four weeks and fill out a qualtrics survey with their subjective experience with the mouthguard.

Investigator's Responsibilities:

If applicable, your approved consent forms and other documents are available online at
http://apps.research.unc.edu/irb/index.cfm?event=home.dashboard.irbStudyManagement&irb_id=19-0324.

New Safety Information should be reported to the IRB, in IRBIS, as per [OHRE SOP 1401](#).

The current data security level determination is Level II. Any changes in the data security level need to be discussed with the relevant IT official. If data security level II and III, consult with your IT official to develop a data security plan. Data security is ultimately the responsibility of the Principal Investigator.

This study was reviewed in accordance with federal regulations governing human subjects research, including those found at 45 CFR 46 (Common Rule), 45 CFR 164 (HIPAA), 21 CFR 50 & 56 (FDA), and 40 CFR 26 (EPA), where applicable.

CC:

Siggi Saemundsson, Pediatric Dentistry
Peter Tawil, Endodontics

APPENDIX C: ATHLETE CONSENT FORM

University of North Carolina at Chapel Hill Consent to Participate in a Research Study Adult Participants

Consent Form Version Date: 02 October 2019

IRB Study # 19-0234

Title of Study: Mouthguards in NCAA Basketball Programs

Principal Investigator: Ibrahim Duqum, BDS, MS

Principal Investigator Department: Restorative Sciences

Principal Investigator Phone number: (919) 537-3964

Principal Investigator Email Address: duqumi@dentistry.unc.edu

Co-Investigator: James Goglia, DDS

SUMMARY OF THE STUDY

The purpose of this study is to better understand what parameters mouthguards make them more likely to be worn by NCAA basketball athletes. Mouthguard usage in NCAA basketball athletes is quite low, even with the relatively high incidence of dental trauma in the sport. By participating in this study, you will receive 4 different mouthguards to wear and report on your experience with the mouthguards. The study will last 4-6 weeks, and you will be required to fill out 4 separate surveys after wearing each mouthguard for a week. There is a potential for a decreased risk of dental trauma throughout the study, as well as for however long you choose to wear the mouthguard after the study is complete. Minor risks of discomfort during mouthguard fabrication do exist, and your participation is completely voluntary. Thank you for your consideration to be involved in the study.

What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary.

You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is obtain subjective feedback from NCAA basketball athletes on three different mouthguard materials. Compliance with mouthguard recommendations in the NCAA is low, and potentially due to the current available designs and materials used to fabricate mouthguards. The information gathered from this study will provide knowledge on how to better protect NCAA basketball athletes from dental trauma.

How many people will take part in this study?

There will be approximately 75-100 people in this research study.

How long will your part in this study last?

Your participation in the study will last about 4-6 weeks. This includes time to fabricate a custom EVA mouthguard. Active participation in the study is exactly 3 weeks once the custom mouthguard is delivered.

What will happen if you take part in the study?

- You will be asked to wear four different mouthguards during all basketball activities
- One of the mouthguards requires an impression of your upper arch to custom fabricate the mouthguard at a dental laboratory
- Each mouthguard will be worn for one week at a time
- At the end of the week, you will be required to complete a survey relating to your experience with that particular mouthguard
- The mouthguards are yours to keep if you participate in the study

What are the possible benefits from being in this study?

Research has demonstrated a clear connection between mouthguard use in NCAA basketball and a reduction in dental trauma incidence. By participating in the study and wearing a mouthguard during basketball activities, you may have a decreased risk of dental trauma. Also, because you get to keep the mouthguards, you may decrease the risks of dental trauma if you choose to continue to wear the mouthguards.

What are the possible risks or discomforts involved from being in this study?

There is occasional discomfort during the process of obtaining an impression of the upper arch. Some people experience gagging during the procedure.

There is a risk of debonding fixed oral appliances (braces, orthodontic retainers, etc.). Precautions can be taken to prevent this from occurring, so please let us know if you have any fixed oral appliances.

How will information about you be protected?

Your data will be de-identified by assigning a code number in exchange for your name. In

addition. Only personnel authorized to be part of the study will have access to this information. Any information exchanged electronically will be done via the UNC secure email system. The software used for the surveys stores the data on an encrypted server, and access to the data is password protected and only accessible by study personnel.

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from being in this study. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. The University of North Carolina at Chapel Hill has not set aside funds to pay you for any such reactions or injuries, or for the related medical care. You do not give up any of your legal rights by signing this form.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have failed to follow instructions or because the entire study has been stopped. If possible at the time of withdrawal, you will still get to keep the three mouthguards.

What if we learn about new findings or new information during the study?

This particular study is not measuring clinical outcomes, but your subjective experience with the mouthguards. The comprehensive data gathered may not be individually applicable to you (i.e. the data says one mouthguard is the most comfortable, but you do not agree), and therefore the data will not be communicated back to you.

Will you receive anything for being in this study?

One Sisu AeroGuard mouthguard, one GameOn mouthguard, one Shock Doctor and one custom dental professionally made EVA mouthguard

Will it cost you anything to be in this study?

It will not cost you anything to be in this study.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study, complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

Signature of Research Participant

Date

Printed Name of Research Participant

Signature of Research Team Member Obtaining Consent

Date

Printed Name of Research Team Member Obtaining Consent

APPENDIX D: TABLES

Table 1: Sports w/ recommended MG use by ADA and IASD

Football	Basketball	Rugby	Soccer	Volleyball	Equestrian
Martial Arts	Softball/Baseball	Track & Field	Ice Hockey	Field Hockey	Inline Skating
Lacrosse	Weightlifting	Racquetball	Boxing	Gymnastics	Water Polo

Table 2: Distribution of the 348 responses by division for questions 7 and 11.

	<u>MG Program?</u>		<u>Trauma Education?</u>	
	Yes	No	Yes	No
Div. I	103 (78%)**	29 (22%)	73 (55%)**	59 (45%)
Div. II	24 (28%)	62 (72%)	31 (36%)	55 (64%)
Div. III	31 (24%)	99 (76%)	53 (41%)	77 (59%)

Table 3: Characteristics of MGs in the study.

	MG Type	Material	Material Thickness	Cost	Warranty (Maximum)
CustomEVA	Custom	Ethylene Vinyl Acetate	3.0 mm	\$99.99	None
Sisu Aero Guard	Self-Adapted	Ethylene Vinyl Acetate + Polycaprolactone Copolymer	1.6 mm	\$24.99	\$35,000
GameOn	Self-Adapted	All-Polyolefin propylene-ethylene copolymer (PEC)	2.0 mm	\$24.99	\$10,000
Shock Doctor Superfit	Self-Adapted	Ethylene Vinyl Acetate with Polyurethane Copolymer	2.0 mm	\$19.99	\$10,000

Table 4: Mean scores (standard deviation) for the four MGs tested

	CustomEVA	Sisu	GameOn	Shock Doctor
Comfort	74.8 (15.8)**	60.5 (23.3)	65.3 (12.5)	58.3 (16.7)*
Fitting Process	74 (16.7)**	61 (14.5)	56.4 (16.3)*	67.6 (13.1)
Breathe	82 (12.8)**	72.2 (15.1)	70.5 (14.4)*	68.7 (19.6)
Drink	74 (22.1)	70.7 (21.2)	74 (13.5)	63.7 (23.2)
Communicate	67.9 (25.06)**	60.8 (17.0)	62.0 (18.9)	51.1 (20.2)*
Focus on B-Ball	86.6 (16.0)	75.1 (18.4)	72.6 (23.4)	72.5 (16.9)
Overall Score	83.8 (13.2)**	64.7 (15.8)*	66.5 (15.5)*	60.2 (16.0)*

Table 5: Comparison of approximate AEs by level of competition.

	Games per Year	Practices per Year	AE per Year	Number of Athletes	Total AEs
NCAA	25 to 35	100	125-135	35,000	4.55M
High School	25 to 35	80	105-115	1M	110M
NBA	82 to 98	25	102-123	500	82,000

Table 6: NCAA Basketball dental trauma incidence.

	Sample Incidence	NCAA Population Incidence
Cohenca et. al. 2007	10.6(M) and 8.3(W) / 100 AS	3,307 (9.4%)
Labella et. al. 2002	.67(M) / 1000 AE	3,015 (8.6%)
Goglia, Manuscript #1	1.26(M) and 0.96(W) / 15 athletes	2,590 (7.4%)

APPENDIX E: FIGURES

Figure 1: Survey response distribution

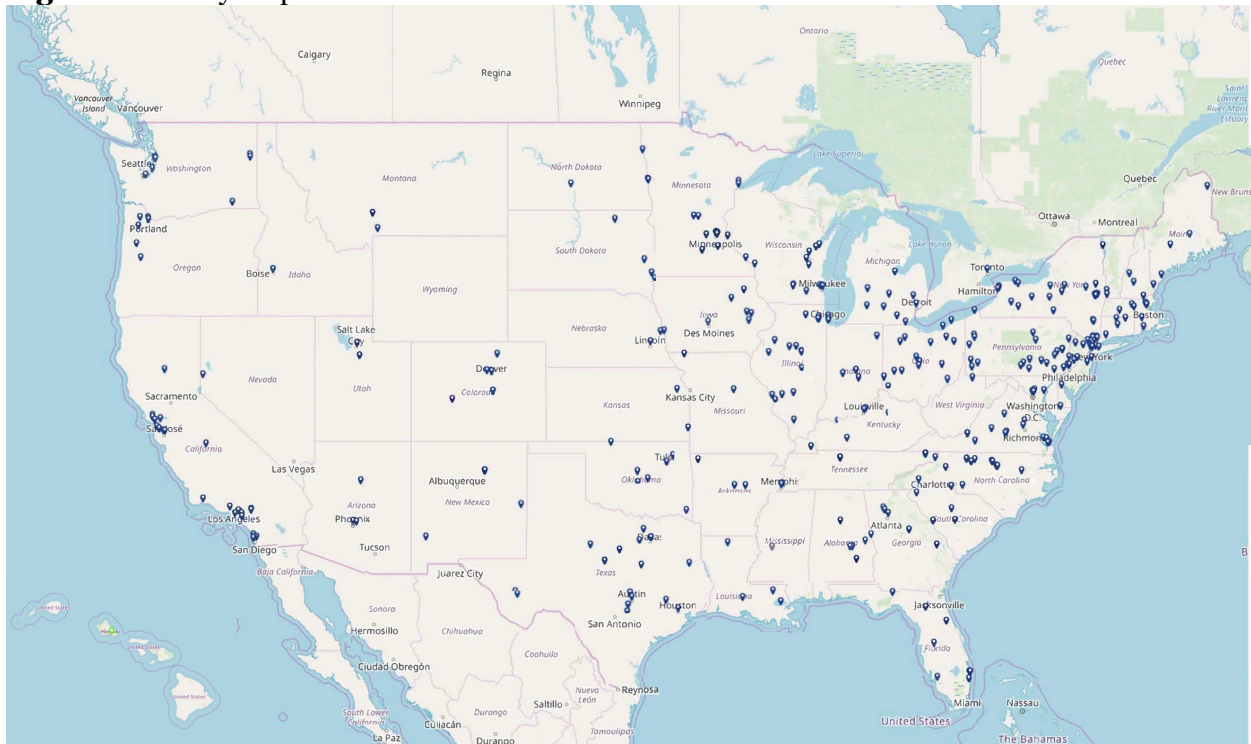


Figure 2: Sisu Aero Guard



Figure 3: GameOn Mouthguard



Figure 4: Shock Doctor Superfit Basketball Mouthguard



Figure 5: CustomEVA Mouthguard



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